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(71) Applicant and
(72) Inventor: O'KEEFFE, Paul, John [AU/AU]; 17 The Tor Walk, Castlecrag, NSW 2068 (AU).

(74) Agent: SPRUSON & FERGUSON; GPO Box 3898, Sydney, NSW 2001 (AU).

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(54) Title: AN ARTICLE OF MANUFACTURE AND A METHOD OF APPLYING A PROTECTIVE GLOVE

(57) Abstract: This invention relates to an article of manufacture including a substrate impregnated or at least partially coated with a moisturising cream base compatible with a protective glove material and containing little or no moisture. A method of applying a protective glove is also disclosed.

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AN ARTICLE OF MANUFACTURE AND A METHOD OF APPLYING A PROTECTIVE GLOVE

Technical Field

The present invention relates to an article of manufacture and to a method of applying a protective glove.

Background of the Invention

Protective gloves such as medical gloves are used in many situations to protect hands from occupational hazards. In 1996, 20.8 billion medical gloves were imported into the US alone of which 90% were made of natural rubber latex and 10% nonlatex synthetic.

Side effects of using such gloves are prevalent including skin irritations and dry skin.

When conducting operations in surgery and in particular for minimising health risks it is necessary for operating theatre personnel to prescrub hands and the lower arm prior to application of medical gloves. The typical scrub time for the first operation of the day is about five minutes. Subsequent scrubs may be shorter but must be sufficient to remove bacteria from the skin. Due to frequent washing with surgical skin cleansers and detergents over prolonged periods, it has been found that hands and arms tend to dry out, the presurgical scrub detergents typically removing natural greases and oils (sebum) such as the cholesterol fraction from the body.

The use of added moisturisers to the scrub detergent to rectify this problem has not been very effective. In addition the application of a sterile moisturising cream immediately before donning the gloves is not desirable due to the hands moving too freely within the glove, the hands being too slippery as the water phase has not had sufficient time to evaporate.

The direct application of a non-slippery anhydrous moisturiser (a cream base) is also undesirable as the cream base is thick and difficult to spread uniformly and areas of skin having a too thick layer of cream base applied are generally slippery within the surgical gloves. Without the use of such moisturisers or cream bases, medical gloves are generally difficult to apply resulting in loose glove material at the finger tips which is a hindrance in performing surgery. To overcome this problem, powdered gloves are known however such gloves are associated with latex allergy and the dusting powders used can be rubbed off and become airborne in use. Cornstarch powders used have a propensity to bind natural latex proteins the powder becoming a means for the transport of natural latex protein allergens. The use of powdered latex gloves is therefore being discontinued.

In this regard health care workers are recognised as comprising a high-risk group for natural latex allergy. Studies of health care workers have demonstrated an appreciable prevalence of natural latex sensitisation as evidenced by natural latex-specific IgE antibodies and/or positive skin tests for natural latex allergy. Experimental studies report that powders such as cornstarch on medical gloves can damage tissue resistance to infection, enhance the development of infection, serve as a potential source of occupational asthma and other respiratory problems and provide a source of natural latex protein exposure to natural latex allergic individuals. Experimental and clinical data demonstrate that natural latex proteins are allergenic, natural latex proteins bind to cornstarch, aerosolised powder on natural rubber latex gloves is allergenic and can cause respiratory allergic reactions. These published studies support the conclusion that airborne glove powder is a threat to individuals allergic to natural rubber latex and may represent an important agent for sensitizing non-allergic individuals. There is also limited published data and clinical experience that cornstarch powder on natural rubber latex gloves may also be a contributing factor in the development of irritation and Type IV allergy. Cornstarch is a strong absorbing powder and has a tendency to cause dryness of the skin leading to cracking and itchiness.

A more permanent method of reducing surface drag of medical gloves is by halogenation of the gloves for example by using chlorine. Such methods are not desirable however as some of the mechanical and physical properties of the natural latex are compromised. Chlorination processes adversely affect shelf life, grip and in-use durability of the glove. In addition strong odours may be present and the gloves may irritate the skin.

It would be desirable at least in preferred embodiments to solve the problem of dry hands and arms of operating theatre personnel by providing a means for replacing skin oils and greases prior to applying protective gloves. It would also be desirable at least in preferred embodiments to provide a means for enabling easy application of protective gloves whilst preventing any allergic reactions to natural rubber latex among workers who use such gloves and other products containing latex.

Object of the Invention

It is the object of the present invention to overcome or substantially ameliorate at least one of the above disadvantages or at least provide a suitable alternative.

Summary of the Invention

According to a first aspect, the present invention consists in an article of manufacture including a substrate impregnated or at least partially coated with a

moisturising cream base compatible with a protective glove material and containing little or no moisture.

According to a second aspect, the present invention consists in a method of applying a protective glove comprising contacting the skin of at least part of the hands and or forearms of an individual with the article of manufacture of the first aspect such that at least a portion of said moisturising cream base is transferred to the skin prior to applying the protective glove.

Detailed Description of the Preferred Embodiments

Preferably the article of manufacture is in the form of wipe or towelette.

Preferably the article of manufacture is sterile. When sterile, the moisturising cream base and any optional ingredients should be compatible with the sterilisation process chosen. Accordingly moisturising cream bases which oxidise or become rancid during the sterilisation process are not suitable. Suitable sterilisation processes include gamma radiation and sterilisation with ethylene oxide gas.

Suitably the protective glove is made of rubber latex or a synthetic material such as vinyl (plasticised PVC), synthetic rubbers (such as neoprene and nitrile) or a synthetic polymer. Protective gloves made from materials other than latex and not containing natural allergens are available but none possess the unique mix of properties offered by natural rubber latex such as high elasticity, high tensile strength and excellent film-forming characteristics, consequently rubber latex gloves are preferred.

By little or no moisture is meant that the moisturising cream base has no water or an amount of water much lower than that of a typical moisturising cream for example 0 to 30wt% of the usual moisture content.

By compatible with a protective glove is meant that the mechanical and physical properties of the glove are not compromised including for example shelf type, grip and in-use durability. The moisturising cream base is suitably safe and effective and does not degrade the glove material.

The moisturising cream base is suitably chosen on the basis of its compatibility with one or more of the surgical scrub solution used, the type of protective glove used and the end user (for example the end user may have hypersensitive skin). Commonly the moisturising cream base is formed from oils and/or greases such as mineral oils and petroleum based materials, vegetable and animal fats and oils or silicone oils and waxes or a combination thereof. Unfortunately some mineral oils and petroleum products are not compatible with latex gloves and when such oils or products are used such cream bases are only suitable for non-latex gloves. Preferably the moisturising cream base is not

oil based. Included as suitable components of moisturising cream bases are paraffinic hydrocarbons (straight or branched chain, saturated or unsaturated) and their common derivatives (fatty alcohols, acids and esters), silicone oils and waxes having chain lengths of from 16 to 60 carbon atoms. Specific examples include mineral oils; petrolatum; waxes including parraffin waxes; microcrystalline waxes; alkyl esters derived from monocarboxylic fatty acids having from 12 to 28 carbon atoms and short chain (C_2 to C_8) monohydric alcohols such as isopropyl myristate, isopropyl palmitate; alkyl esters derived from fatty alcohols (C_{12} to C_{28}) and short chain acids; fatty acids, fatty alcohols and fatty alcohol ethers having from 12 to 28 carbon atoms in at least one chain such as stearic acid, cetyl alcohol, cetostearyl alcohol, and cetomacrogol 1000 (polyethylene glycol 1000 monoacetyl ether), ethoxylated and propoxylated fatty alcohols such as laureth-23 and steareth-2; glycerides, triglycerides, acetoglycerides and ethoxylated glycerides of C_{12} to C_{28} fatty acids; other fatty esters of polyhydroxy alcohols; lanolin and its derivatives; polysiloxanes such as dimethicone and other conventional emollients such as glycerin and propylene glycol and other polyols.

More specific examples of moisturising cream bases include (a) Temovate (Glaxo Wellcome) Emollient Cream (a mixture of cetostearyl alcohol, isopropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate and imidurea as a preservative, (b) Moisturel® (Westwood-Squibb) Emollient-Moisturizer (a mixture of white petrolatum 30%, dimethicone 1%, carbomer 934, cetyl alcohol, diazolidinyl urea, glycerin, Kathon CG, laureth-23, magnesium aluminium silicate, PVP hexadecane copolymer, PG dioctanoate, sodium hydroxide and steareth-2), (c) Hyderm cream (a mixture of cetostearyl alcohol, purified water, propylene glycol and sodium lauryl sulfate), (d) Sorbolene with Glycerin 10% cream (contains cetomacrogol cream, aqueous B.P., glycerin (glycerol) 10%, preserved with methyl hydroxybenzoate B.P. 0.2% and propyl hydroxybenzoate B.P. 0.1%) and (e) Microshield® (Johnson& Johnson medical) moisturising lotion base containing stearic acid, glycol stearate, isopropyl palmitate, parrafin liquid, collagen amino acids, dl-alpha tocopherol acetate, aloe barbadensis gel, cocamidopropyl PG-dimonium chloride phosphate, PEG-75 lanolin dimethicone, cetyl alcohol, propyl hydrobenzoate, carbomer, triethanolamine, quaternium-15, triclosan and methylhydrobenzoate (this lotion base is compatible with latex and chlorhexidine, a common surgical scrub component, and is suitable for gamma radiation).

Preferred moisturising cream bases are those containing pure cholesterol and/or wool alcohols (with not less than 28% cholesterol) including Ointment of Wool Alcohols

(B.P.) containing wool alcohols 6% with hard paraffin, white soft paraffin, yellow soft paraffin and liquid paraffin. Another preferred cream base is Eucerin (anhydrous) available from Beiersdorf Australia Ltd which is a wool alcohol ointment B.P containing highly purified wool alcohol prepared from the unsaponifible fraction of wool fat and containing free alcohols consisting of approximately 30% cholesterol (and typically not less than 28% cholesterol) with the triterpine alcohols lanosterol and agnosterol, and other aliphatic alcohols. In any of these cream bases it may be desirable to reduce or substitute any paraffin content with for example a suitable vegetable oil for latex compatibility. As a preferred example of a moisturising cream base is cholesterol dissolved in a vegetable oil such as jojoba oil with an antioxidant such as vitamin E.

Suitably the moisturising cream base is impregnated in or coated on the substrate in an amount sufficient to enable it to be transferred to the skin and in an amount less than that which would cause the skin to become too slippery and cause undue movement of the protective glove on the fingers. Most preferably the substrate is impregnated with up to four times its weight in moisturising cream base, even more preferably up to three times its weight.

Suitably the substrate is paper-like and can be made from a non-woven material, paper, cotton, rayon, a woven material, wadding, felt, sponge or a mixture thereof. Suitably the substrate is chosen on its stability with respect to the sterilisation process chosen. For radiation stability compounds are chosen for the substrate that preferably contain benzene rings which can be part or a branch to a main chain (compounds are avoided with contain triple bonds, double bonds in a main chain and high energy (stable) side branches). Suitable polymers for forming the substrate which are capable of being irradiated include polystyrene and its copolymers such as ABS (thermoplastic terpolymer from acrylonitrile), SAN (thermoplastic copolymer from styrene and acrylonitrile), HIPS (high impact polystyrene), polyethylene, low density polyethylene (LDPE), linear low density polyethylene (LLDPE), high density polyethylene (HDPE), polyesters and PETG (polyethylene terepthalate glycol), polycarbonate and alloys, polysulfone, PVC (polyvinylchloride) flexible and semi-rigid (colour corrected), polyurethanes, "high-end" engineering resins, PEK (polyether ketone), PEEK (polyether ester ketone), polyetherimides, thermosets such as epoxies, phenolics, polyimides, polyurethanes, polyesters, elastomers such as TPE (thermoplastic elastomer), SEBS (styrene-ethylene/butylene-styrene triblock polymer), TPO (thermoplastic olefinic elastomer), natural isoprene, EPDM (elastomeric terpolymer from ethylene, propylene and a nonconjugated diene), silicone, urethane and nitrile, polyamides such as nylons especially

12. 11. 6/12 and 6/10. polypropylenes and copolymers (radiation stabilised). fluoroplastics (other than PTFE (polytetrafluoroethylene) and FEP (thermoplastic copolymer from tetrafluoroethylene and hexafluoroethylene)) such as PVDF (polyvinylidene fluoride). PCTFE (polychlorotrifluoroethylene) and PETFE (polyethylene-tetra-fluoroethylene).

The moisturising cream base may also suitably contain optional ingredients such as an antiseptic. Alternatively an antiseptic may be included in the prescrub solution. such antiseptics remain as a residue on the skin. In either situation it is desirable that the moisturising cream base is compatible with the antiseptic residue or the antiseptic included in the moisturising cream base. Other optional ingredients include emulsifiers. skin conditioners. thickeners. pH adjusting agents. hemectants. colourants. fragrances. preservatives and antioxidants. A suitable antioxidant is Vitamin E.

The article of manufacture can be prepared in a clean sterile environment. For example the substrate can be immersed in the cream moisturizing base and any excess suitably removed. Alternatively the moisturising cream base may be in the form of a solution which is allowed to evaporate. The article of manufacture can be presented in a peel-apart pack. Suitably the article of manufacture in the form of a wipe or towelette is folded into a compact form prior to being sealed within a package. Preferably the towelette is interleaved with sheets of grease-proof paper. folded and placed in a peel-open pouch (preferably a plastic pouch). packaged and gamma irradiated for a shelf life of up to 5 years. Alternatively the towelette may be placed in a pervious envelope and sterilised with ethylene oxide.

The article of manufacture can be applied to a user's skin as soon as possible and preferably immediately after washing and hand drying and rubbed over the hands and forearms resulting in a uniform thin layer of the moisturising cream base on the skin. The gloves and where necessary sterile gown can then be donned.

By use of the invention it is possible to apply a uniform thin layer of a moisturising cream base to skin prior to donning medical gloves which gloves are then easier to apply. The pharmaceutical composition of the present invention produces a moisturising effect on the skin because the gloves are applied as soon as possible after application. If gloves were not applied the moisturising effect would be inferior to that of a standard moisturising cream which contains more water. Use of the invention results in the moisturising cream base being applied to the skin which is then occluded by gloves and gown. Occlusion of the skin promotes absorption of the cream base into the skin.

Examples

Example 1

Towellettes in accordance with the present invention containing wool alcohols were prepared on a small scale as follows. Paper was slit to 12cm width and rolled. The paper roll was then placed on an appropriate manufacturing station where it was unrolled and passed through a vat of the wool alcohol which had previously been melted by heating to about 80°C. The oiled paper was then passed through rollers to remove excess oil and then onto a lamination stage where a 13cm wide strip of grease-proof paper was applied to both the top and bottom surfaces, overlapping at each edge. The trilaminate was then passed through motorised rollers to a guillotine station where it was cut to 10cm lengths, the lengths falling on a fast moving conveyor belt and then to a paper folding station. The folded portions were then stacked inside a tubular container and when full passed to the next station where individual folded portions were removed and placed on another conveyor bearing a bilaminar plastic film. The timing of the placement of the folded portion was controlled by timing marks printed on the plastic film passing over a light-sensing diode. A second bilaminar plastic film was applied to the top surface and the composite layers passed onto the next station where the laminate was heat fused and cut into pouches each containing a single folded towelette. The pouches were then placed in boxes and gamma irradiated.

Example 2

An article of manufacture according to the invention was prepared as follows. A cellulose paper Dextex Ultrawrap towellette (Dexter Corporation of Connecticut) supplied by Dräger Australia and measuring 12cm by 10 cm was weighed and found to have a dry weight of 0.5gms. The towellette was then immersed in a molten wool alcohol ointment (Eucerin) which had been melted at a temperature of about 80°C (Eucerin has a melting point of not below 58°C). The towellette impregnated weight was 1.4gms. The towellette was then applied by a user to the hands and lower arms and reweighed. The towellette after use had a weight of 1.2 gms. The user then applied a powder-free surgical glove. It was found that the glove was easy to put on and easy to use. No additional lubrication was required and the hands were not slippery within the gloves.

It will be appreciated by those skilled in the art that the invention can be embodied in other forms. For example the invention is not limited to use in surgical situations but

can be used in non-sterile situations where it is necessary to use protective gloves for example in dental surgeries and childcare centres.

Industrial Applicability

The present invention provides an article of manufacture including a substrate impregnated or at least partially coated with a moisturising cream base compatible with a protective glove material and containing little or no moisture. A method of applying a protective glove is also disclosed.

CLAIMS

1. An article of manufacture including a substrate impregnated or at least partially coated with a moisturising cream base compatible with a protective glove material and containing little or no moisture.

2. An article of manufacture according to claim 1 in the form of a wipe or towellette.

3. An article of manufacture according to claim 1 which is sterile.

4. An article of manufacture according to claim 1 which is compatible with rubber latex or a synthetic glove material.

5. An article of manufacture according to claim 1 wherein the moisturising cream base is formed from oils and/or greases.

6. An article of manufacture according to claim 5 wherein the oils and/or greases are mineral oils, petroleum products, vegetable oils or waxes, animal oils or waxes, silicone oils or waxes or a combination thereof.

7. An article of manufacture according to claim 5 wherein the moisturising cream base is formed from cholesterol and/or wool alcohols.

8. An article of manufacture according to claim 7 wherein the moisturising cream base is formed from cholesterol, jojoba oil and vitamin E.

9. An article of manufacture according to claim 1 wherein the substrate is impregnated with up to four times its weight in moisturising cream base.

10. An article of manufacture according to claim 1 wherein the substrate is made from a non-woven material, paper, cotton, a woven material, wadding, felt, sponge or a mixture thereof.

11. A method of applying a protective glove comprising contacting the skin of at least part of the hands and/or forearms of an individual with the article of manufacture according to any one of the preceding claims such that at least a portion of said moisturising cream base is transferred to the skin prior to applying the protective glove.

12. A method according to claim 11 wherein the article of manufacture is applied immediately after washing and hand drying.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/00909

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[7]: A 47K 7/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A47K 7/03

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 32793, A, (Procter and Gamble) 29 July 1981 see whole document	1-12
X	FR 2538238, A, (Scerab) 29 June 1984 see whole document	1-12
X	DE 29812117, A, (Offen) 8 October 1998 see whole document	1, 5, 6

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200
WODEN ACT 2606 AUSTRALIA
E-mail address: pct@ipaustralia.gov.au
Facsimile No.: (02) 6285 3929

Authorized officer

B.R. DASHWOOD
Telephone No.: (02) 6283 2121

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Derwent Abstract Accession No 97-458025/43, Class P28, CN 1117835, A, (WU) 6 March 1996	
A	WO 95/23009, A, (Sof) 31 August 1995	
A	FR 2378489, A, (Miol-Flavard) 25 August 1978	

BNSDOCID: <WO___0106541A1_1_>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU 00/00909

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
EP	32793	A2	29/07/1981	AU	66290/81	A1	23/07/1981
				CA	1174405	A1	18/09/1984
FR	2538238	A1	29/06/1984	NONE			
DE	29812117	U1	19/11/1998	NONE			
WO	9523009	A1	31/08/1995	AU	19312/95	A1	11/09/1995
				AU	705862	B2	03/06/1999
				CA	2183661	AA	31/08/1995
				US	5702992	A	30/12/1997
FR	2378489	A1	25/08/1978	NONE			

END OF ANNEX